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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,375	12/08/2003	Tameo Ashida	163852020100	8135

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EXAMINER	
SUNDARARAMAN, VIKRAM P	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,375	ASHIDA ET AL.	
	Examiner	Art Unit	
	Vikram P. Sundararaman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. **Claims 1-2** are rejected under 35 U.S.C. 102(a) as being anticipated by Kehr et al, US 5,752,235, hereinafter referred to as Kehr.

3. As to **Claim 1**, Kehr teaches an "electronic medication monitoring device" [Column 1, Line 54] (medicine case) with:

> "a plurality of medication compartments in which are inserted a plurality of drawers which may each be used to store a different medication" [Column 2, Lines 9-10] (medicine storage means for storing one or plural medicines to be taken each time by the user in divided portions);
>
> "is capable of accepting, storing a medication signal as well as physician's instructions" [Column 1, Lines 56-58] and "provides for ease of entry of a medication schedule" [Column 1, Lines 60-61] (medication instruction storage means for storing instruction of medication entered from outside);

"relies upon that schedule(s) to indicate to the user when medication is to be taken" [Column 2, Lines 16-17] (medication instruction means for instructing the medicine to be taken from the divided portions stored in the medication storage means on the basis of the medication instruction of the medication instruction storage means);

"the opening and closing of the various compartments is sensed by the microprocessor through the actuation of individual switches associated with each compartment" [Column 4, Lines 58-60] (medication detection means for detecting taking of the medicine instructed by the medicine instruction means);

"each medication alert and associated taking or skipping of medication is stored in the microcontroller's random access memory (RAM), so that the patient can later review when and if pills were presumably taken or skipped" [Column 4, Lines 60-64] and "the memory storing the prospective and retrospective information may be extended, by the use of additional RAM, to provide a longer time period of review, and an electronic output may be provided" [Column 5, Lines 6-9] (storage output means for storing the medicine taking record detected by the medication detection means, and issuing to outside); and

"information [that] can be directly transferred to a computer or to a printer for analysis" [Column 5, Lines9-10] (display means for displaying the medicine taking record stored in the storage output means)

4. **As to Claim 2**, Kehr further teaches:

"a separate closure (for example a lid) for opening and closing each compartment" [Column 4, Lines 31-33] (the medicine storage means is constituted of a plurality of compartments having lids for storing in divided portions according to each medicine taking timing by the user);

"the device indicates the compartment of the device from which the medication is to be taken and the quantity of medication" [Column 2, Lines 18-20] (the medication instruction means instructs the compartment storing the medicine to be taken"; and

"when the lid or drawer is moved to open the compartment, a switch operating the electrical circuitry of the signaling system, turns off the visual medication alert signal and/or the audible alarm" [Column 34-37] and "the unit can optionally be designed to turn off the alert after the drawer is closed" [Column 2, Lines 29-30] (the medication detection means detects opening and closing of the lid of the compartment).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kehr in view of Weinstein et al, US 6,564,945 B1, hereinafter referred to as Weinstein. Kehr disclosed the claimed invention as discussed in Items 3 and 4 of this action. What Kehr does not teach is a medicine storage means constituted of a plurality of slits holding one pouch each of the medicine to be taken, the medication instruction means instructs one of plural slits holding the pouches to be taken, and the medication detection means detects taking of the pouch out of the slit. In this regard, Weinstein teaches a "unified medication assemblage" wherein "the box embodiment includes a box and a plurality of event modules. Each event module is either a blister pack or a pouch and is identified by an event indicia." [Column 3, Lines 10-12]. (plurality of slits holding one pouch each) Furthermore, Weinstein teaches "the indicia represent events and medications. One set of indicia, indicates the time of day or the activity with which the dosages of each event module is to be taken" [Column 4, Lines 49-52]. (medication instruction means) Since Kehr already teaches detection of taking medication, it would have been obvious to one skilled in the art at the time of the invention to modify Kehr by the teachings of

Weinstein wherein the medication would be stored in a plurality of slits, holding pouches of medication, with instructions on when to administer the medicines along with a detection means of Kehr to detect when a pouch is removed from a slit.

7. **Claims 4-7 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerr, II et al, US 2004/0139048 A1, hereinafter referred to as Kerr, in view of Kehr.

8. As to **Claim 4**, Kerr teaches a remotely monitored medical system, which includes "an RMMS ... 'smart pillbox' as shown in Fig. 1" and that "each RMMS contains at least one medication matrix comprised of multiple dosage containment units (DCUs)." [Paragraph 0029] Kerr further discloses "in still yet an another embodiment, the system includes a digital blood pressure monitor for recording a patients blood pressure." [Paragraph 0019] Kerr also teaches that "if the RMMS unit has other peripheral monitoring systems, such as a digital thermometer, a digital scale, a digital auto-inflating blood pressure monitor, or other digital health or fitness monitors... the optional monitors interface directly to the Medication System's data system. During operation, they capture the measurement data, and transfer it to the Medication System's data system for immediate storage into temporary memory." [Paragraph 0046]. Furthermore, Kerr teaches that "regardless of what peripheral are attached to the RMMS... the data transmission is designed to contain all relevant data generated by the RMMS unit." [Paragraphs 0048 and 0049] Kerr also teaches "each of the DCUs is also connected to a door sensor or interface which monitors the open/close status of a

door." [Paragraph 0030] What Kerr does not teach is a medication instruction storage means for storing instruction of medication entered from outside; medication instructions means for instructing the medicine to be taken from the divided portions stored in the medicine storage means on the basis of the medication instruction of the medication instruction means; and a display means for displaying the blood pressure value and the medicine taking record stored in the storage output means. Kehr teaches the elements of a device for monitoring medication of a patient as discussed above in Paragraphs 2-4 of this action, including: a medication storage means, a medication instruction storage means, a medication instructions means, a medication detecting means, a storage output means, and a display means. Since both Kerr and Kehr both disclose a medication management device it would have been obvious to one with ordinary skill in the art at the time of the invention to modify Kerr with the teaching of Kehr to also include a medication instruction storage means, a medication instruction means, and a display means.

9. **Claim 5 and Claim 6** are rejected in view of the disclosed invention as discussed and in further view that the examiner takes official notice that it is well known in the art (for example, US 6,447,457; US 6,443,906; US 6,251.080) for blood pressure monitors, such as the peripheral digital blood pressure monitor of Kerr, would record and store the systolic blood pressure value, the diastolic blood pressure value, pulse rate and time and date of measurement. It would therefore be obvious to one with ordinary skill in the

art to modify the disclosed invention with a peripheral blood pressure monitor that stores, outputs, and displays these data.

10. **Claim 7** is rejected since all of the components of the medication management system disclosed have been previously discussed.

11. **Claim 9** is rejected since the claimed invention has all of the elements as discussed previously wherein the entire apparatus may be called a blood pressure monitor with the ability to measure blood pressure, store both blood pressure measurement data, medication information storage and a displaying the same.

12. **Claim 8,** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kehr as applied to Claims 4-7 & 9 above, and further in view of Lin et al, US 2003/0216624 A1, hereinafter referred to as Lin. Kehr and Kerr describe the disclosed invention as discussed previously. Kerr further teaches "the RMMS of the current invention is also designed to be remotely monitored and/or operated. Accordingly, each RMMS is also provided with a transmitter 6 such that the status of each DCU 1 may be transmitted to a remote receiver (not shown) and thereby the status of the RMMS and each DCU remotely monitored. Although as shown in FIG. 1 the transmitter 6 may comprise a hardwired interface such as through a modern connection to an external data or telephone line, the RMMS may also comprise a wireless transmitter, such as, for example, a two-way pager system, a cellular system, a suitable RF radio frequency, or

any other suitable data transmission system, such as over the Internet via an email or web-broadcast system. In addition to the actual transmitter, the data generated for transmission by an RMMS unit of the current invention can be in any suitable format." In addition, Lin discloses a "system for monitoring medical data, a terminal device for measuring and storing medical data, a medicine container and a holder for medical containers." Lin teaches a "central computer can be typically a personal computer located at a pharmacy or at a doctor's office. Such a system has a number of advantages. A first advantage is, that user specific programs can be loaded into the terminal device." [Paragraph 0021]. Since Lin also describes a medication management system with an associated medicine case, it would have been obvious to one with ordinary skill in the art at the time of the invention, to include the further teachings of Kerr in further view of the teachings of Lin to include medication instruction means and external display means at controllers installed at a medical institution comprising communication means for transmitting and receiving between the controllers and the medicine case with a blood pressure measuring function via public lines.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vikram P. Sundararaman whose telephone number is 571.272.3351. The examiner can normally be reached on M-F, 730am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VPS

ROBERT L. NASSER
PRIMARY EXAMINER